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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,775	09/15/2003	Andrea Marinello	930071-2001	2185
20999 7590 06/29/2007 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER GHALL, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/662,775	Applicant(s) MARINELLO ET AL.	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/29/07.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
4a) Of the above claim(s) 1-12 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and foreign priority document, both filed 03/29/2007.

Claims 1-33 are pending

Claims 1-12 and 31-33 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/06/2006.

Claims 13-30 are included in the prosecution.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The following rejections have been overcome by virtue of applicants' amendment and remarks:

- (A) The rejection of claim 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

(B) The rejection of s 13-30 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13 and 25 are amended to recite that "compress affixed to said inflatable elastic pad", and applicants are referring to figure 12 and page 10 for support. However, figure 12 does not show the device parts connected or the relation between the parts, it only shows the individual parts of the device. In page 10, lines 3-17, figure 12 is described as follows:

"Figure 12 illustrates an exploded view of the first and second embodiments of present invention. In the first embodiment of the present invention, facial mask (10) having bands (11) and (12) is affixed to first membrane (21). First membrane (21) is attached to second membrane (22) forming a compression chamber. Rubber tube (30) having small rubber pump (31) with a valve, is connected to pump air into the compression chamber. Compress (40) soaked in water at 10°C,

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containing a revulsive, or a compress comprising an active ingredient such as an allyl isothiocyanate, is subsequently fitted adjacent to second membrane (22)".

Therefore, the bands 11 and 12 are affixed to membrane 21 and not to the inflatable elastic pad. Figure 12 does not show inflatable elastic pad at all. No disclosure of affixation of the compress to the inflatable elastic pad as recited by the claims.

Additionally, claim 19 is amended to recite "manual pump", nowhere applicants disclosed manual pump. Applicant refer to page 7, line 10 for support, while that text recites "rubber pump", and not manual pump.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

The following rejections are discussed in details in the previous office action, and are maintained for reasons of record:

4. Claims 13-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Claims 13 and 25 do not describe where the compress is located in the device in relation to the mask and the inflatable pad. No correlation between the position of the mask and the inflatable pad to the compress.

Claims employing language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. This expression represents only an invitation to experiment regarding possible means.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention.

Response to Arguments

5. Applicant's arguments filed 03/29/2007 have been fully considered but they are not persuasive. Applicants are referring to figure 12, and page 10 for description of correlation of the parts of the device to each other. Applicants further argue that claims 13 and 25 are amended to recite that "compress affixed to said inflatable elastic pad".

With careful recourse to figure 12 and page 10, it is argued that figure 12 does not show the device parts connected or the relation between the parts, it only shows the individual parts of the device. In page 10, lines 3-17, figure 12 is described as follows:

"Figure 12 illustrates an exploded view of the first and second embodiments of present invention. In the first embodiment of the present invention, facial mask (10) having bands (11) and (12) is affixed to first membrane (21). First membrane (21) is attached to second membrane (22) forming a compression chamber. Rubber tube (30) having small rubber pump (31) with a valve, is connected to pump air into the compression chamber. Compress (40) soaked in water at 10°C, containing a revulsive, or a cress comprising an active ingredient such as a allyl isothiocynate, is subsequently fitted adjacent to second membrane (22)".

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Therefore, the bands 11 and 12 are affixed to membrane 21 and not the inflatable elastic pad. Figure 12 does not show inflatable elastic pad at all. No disclosure of affixation of the compress to the inflatable elastic pad as recited by the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 13, 15-25, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,262,711 ('711) in view of US 4,93,401 ('401).

US '711 teaches medical nebulizer used for treating sinusitis (col.1, lines 1-5). The nebulizer comprises mask, medicament in a chamber, and pressure provided by motor to vaporize the medicine to small pores of the sinus tract (col.1, lines 13-39). The medicaments are contained in a sponge member (col.3, lines 21-23).

Although US '711 suggests pressure to deliver of the medication, however, it does not teach the inflatable pad as required by claims 13 and 25, or means to secure the mask to the person's head as claimed in claims 20 and 29.

US '401 teaches mask to deliver medicament to the underlying tissues, the mask comprises medicament impregnated in a pad and delivered by force of inflatable elastic pump in order to concentrate the medicaments and inject them as near as possible to the injured or inflamed part (abstract; col.2, lines 55-61, col.3, lines 24-28, 39-40; figure 1). Figure 3 shows the mask is supplied by strips to affix the mask to the patient's head.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising mask, medicament contained in a sponge member, and pressure to deliver the medicine to the sinuses as disclosed by US '711, and use the inflatable elastic pump to deliver the medicaments from the sponge member as disclosed by US '401, motivated by the of US '401 that such a pressure elastic pump concentrates the medicaments and injects them as near as possible to the injured or inflamed part, with reasonable expectation of having device comprising mask, medicament contained in a sponge member, and elastic pump to deliver the medicine as near as possible to the injured or inflamed part including sinuses with great success. Additionally, one having ordinary skill in the art would have added

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the strips used to affix the mask disclosed by US '401 to the mask of US '711 motivated by the teaching of US '401 that such strips secure the device to the head of user, with reasonable expectation of having device comprising mask that has strips to secure the mask to the face of the user.

Response to Arguments

9. Applicant's arguments filed 03/29/2007 have been fully considered but they are not persuasive. Applicants argue that US '711 teaches introducing volatized medicaments to the respiratory system and does not suggest absorption of any medicament to bones underlying mucous membranes. US '401 fails to cure the deficiencies of US '711 as it is directed to an apparatus applicable to the external part of the orbital cavity to introduce medicaments for the cure of internal injuries, wounds, or inflammation to the ocular organs and the central nervous system, and not to the underlying bones in the sinuses. There is no suggestion or motivation to modify the reference or to combine reference teachings either in the references themselves or in the general knowledge available to one of ordinary skill in the art; and there is no reasonable expectation of success. The combination of US '711 and US '401 fails to teach or suggest all of the instant claim limitations, specifically the absorption of the active ingredients to bones underlying mucous membranes in a sinus of the wearer.

In response to these argument, applicants' attention are directed to the scope of claim 13 that is directed to device, and claim 25 that is directed to method of its use,

and all the elements of the device are disclosed by the combined teaching of the references. The method claim 25 requires one step of securing the device to the person's head which also disclosed by the references. US '711 is directed to treating sinuses, and at col.1, lines 36-39, teaches that the medicament penetrates the small pores of the sinus tracts, as required by the present device and method. The claims included in the rejection do not exclude volatilized medicaments. US '401 is relied upon for the sole teaching delivering of medicament impregnated in a pad by force of inflatable elastic pump to the injured or inflamed part, and also for teaching means for securing the device to the head. The test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). US '711 and US '401 are analogous art and both directed to delivery of medicament from device mounted to the head to the underlying bone, their combination is proper.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising mask, medicament contained in a sponge member, and pressure to

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deliver the medicine to the sinuses as disclosed by US '711, and use the inflatable elastic pump to deliver the medicaments from the sponge member as disclosed by US '401, motivated by the of US '401 that such a pressure elastic pump concentrates the medicaments and injects them as near as possible to the injured or inflamed part, with reasonable expectation of having device comprising mask, medicament contained in a sponge member, and elastic pump to deliver the medicine as near as possible to the injured or inflamed part including sinuses with great success. Additionally, one having ordinary skill in the art would have added the strips used to affix the mask disclosed by US '401 to the mask of US '711 motivated by the teaching of US '401 that such strips secure the device to the head of user, with reasonable expectation of having device comprising mask that has strips to secure the mask to the face of the user.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a) as the invention as a whole is taught by the combined teaching of the references.

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10. Claims 14 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '711 in view of US '401, and further in view of US 5,248,504 ('504).

The combined teachings of US '711 and US '401 are discussed above. However, the combined teachings of the references do not teach allyl isothiocyanate as an active ingredient to be delivered to the sinuses as claimed by claims 14 and 26.

US '504 teaches method for treating nasal sinuses dysfunction comprising applying allyl isothiocyanate to the affected mucosa by spraying (abstract; col.2, lines 20-22, 35-39, 50-52).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising mask, medicament contained in a sponge member, and elastic pump to deliver the medicine as near as possible to the injured or inflamed sinuses as disclosed by the combined teachings of US '711 and US '401, and replace the medicament by allyl isothiocyanate disclosed by US '504, motivated by the teaching of US '504 that allyl isothiocyanate treats nasal sinuses dysfunction when applied to the affected mucosa, with reasonable expectation of having device comprising mask, allyl isothiocyanate contained in a sponge member, and elastic pump that treats nasal sinuses dysfunction with great success.

Response to Arguments

11. With regard to the rejection of the claims 14 and 26 under 35 U.S.C. 103(a) as being unpatentable over US '711 in view of US '401, and further in view of US 5,248,504 ('504), applicant has failed to traverse the rejection and the response is

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considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

Isis A Ghali
Primary Examiner
Art Unit 1615



ISIS GHALI
PRIMARY EXAMINER